UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,613	04/12/2004	Philip J. Scarpace	36689.26	5010

27683 7590 01/11/2007
HAYNES AND BOONE, LLP
901 MAIN STREET, SUITE 3100
DALLAS, TX 75202

EXAMINER	
SALVOZA, M FRANCO G	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,613	SCARPACE ET AL.	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 22, 23, 35 have been amended.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2006 has been entered.

Claims 1-12, 21-40 are pending and under consideration.

Claim Rejections - 35 USC § 101

WITHDRAWN

Claim 29 was rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicant contends that after amendment the rejection is obviated.

Applicant's arguments are considered and found persuasive. The rejection is withdrawn.

Claim Objections

WITHDRAWN

Claim 37 was objected to for containing a misspelling.

Applicant contends that after objection the rejection is obviated.

Applicant's arguments are considered and found persuasive. The objection is withdrawn.

Claims 31, 32 were objected to for reciting instructions of the kit.

Applicant contends that the objection is improper.

Applicant's arguments are considered and found persuasive. The objection is withdrawn.

Claim Rejections - 35 USC § 112

WITHDRAWN

Claims 1-12, 21-30, 35, 35 were rejected under 3 5 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of rAAV-POMC compositions to the hypothalamic arcuate nucleus of rats, does not reasonably provide enablement for the other claimed methods of delivery (for example, intramuscular).

Applicant contends that after amendment the rejection be withdrawn.

Applicant's arguments are considered and found persuasive. The rejection is withdrawn.

Claim Objections

NEW

Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 22 recites the composition of claim 10, formulated for intracerebroventricular administration to a mammalian brain.

Claim 22 is dependent on claim 10, reciting formulation for administration to a human. To recite a composition for any mammalian brain as dependent from a composition for a human is improperly dependent for broadening the scope to recite "any mammalian brain" when the previous claim only recites humans.

Claim Rejections - 35 USC § 103

WITHDRAWN

Claims 1-7, 11, 12, 21, 24, 26-30, 31-40 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pritchard et al. in view of Paterna et al.

Claims 1-9, 21, 26 and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pritchard et al. and Paterna et al. in view of Lasic et al.

Claims 1-7, 11, 12, 21-24, 26-28, 30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pritchard et al. and Paterna et al. in view of Keir et al.

Claims 1-8, 11, 12, 21-24, 26-28, 30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pritchard et al. and Paterna et al. in view of Russell et al.

Applicant contends that a reference available under 102(a) can be removed as prior art by submission of a suitable antedating affidavit under 37 C.F.R. 1.131 demonstrating invention in the U.S. prior to the date of publication of the Section 102(a) reference; applicant submitted an affidavit demonstrating such invention.

The affadavit under 37 CFR 1.131 filed October 23, 2006 is sufficient to overcome the rejection of claims 1-7, 11, 12, 21, 24, 26-30, 31-40 based upon Pritchard et al. in view of Paterna et al. Additionally, the subsequent 35 U.S.C 103 rejections combining Pritchard et al. in

view of Paterna et al. in view of various references fall as a result as well, and the rejections are withdrawn.

Claim Rejections - 35 USC § 103

NEW

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 5, 6, 7, 10-12, 21-38, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pritchard et al. in view of Wilson et al. (WO/2000/28061) (Note that the publication date of Wilson et al. is a 102(b) date.)

Claim 1 recites a composition comprising recombinant adeno-associated viral (rAAV) vector that comprises a nucleic acid segment encoding a pro-opiomelanocortin polypeptide operably linked to a promoter capable of expressing said segment in a host cell that comprises said vector, wherein said polypeptide activates the central melanocortin pathway in a mammal that expresses said vector.

Claims 2, 4, 5, 6, 7, 10, 25, 26 recite the composition of claim 1, wherein said rAAV vector further comprises an enhancer sequence operably linked to said nucleic acid segment; wherein said nucleic acid segment encodes a mammalian pro-opiomelanocortin polypeptide; wherein said promoter is an inducible promoter; further comprising a pharmaceutically-acceptable excipient, diluent, or buffer; wherein said rAAV vector is comprised within an rAAV

virion; formulated for administration to a human; comprised within an isolated human host cell; comprised within an AAV virion or viral particle.

Claims 11, 24, 26, 27, 28, 29, 30, 31, 33, 34, 37, 40 recite the composition of claim 1, comprised within a kit for diagnosing, preventing, treating or ameliorating the symptoms of a pro-opiomelanocortin polypeptide deficiency condition in a mammal; comprised within an isolated mammalian host cell; comprised within an AAV virion or viral particle; comprised within a plurality of infectious AAV particles; a virion or viral particle for the transfection of mammalian cells, comprising the composition of claim 1; an isolated mammalian host cell comprising the composition of claim 1; a kit comprising: (a) the composition of claim 1; and (b) instructions for using said kit; a kit comprising in suitable container means the composition of claim 1; and instructions for using said kit; wherein said mammal has been diagnosed with obesity, adiposity, or suffers from excessive body weight gain; wherein said mammal has a pro-opiomelanocortin polypeptide deficiency condition that results in polyphagia, hyperinsulinemia, adiposity, an eating disorder, or body weight gain in said mammal; wherein said adeno-associated viral vector is a serotype 1, serotype 2, serotype 3, serotype 4, serotype 5, or serotype 6 vector; wherein said promoter comprises a chicken beta-actin promoter.

Claim 22, 23 recite the composition of claim 10, formulated for intracerebroventricular administration to a mammalian brain; formulated for intracerebroventricular administration to the arcuate nucleus of a human hypothalamus.

Claim 38 recites the composition of claim 2, wherein said enhancer sequence comprises a cytomegalovirus immediate early enhancer sequence.

Claim 21 recites the composition of claim 5, wherein said promoter is a chicken beta-actin promoter.

Claim 35 recites the composition of claim 6, formulated for intracerebroventricular administration to said mammal.

Claim 12 recites a recombinant adeno-associated viral particle comprising a nucleic acid segment encoding a pro-opiomelanocortin polypeptide operably linked to a promoter capable of expressing said segment in a host cell that comprises said vector, wherein said polypeptide activates the central melanocortin pathway in a mammalian cell that expresses said vector.

Claim 32 recites a kit comprising, in suitable container means: (a) a composition that comprises an adeno-associated viral vector comprising a nucleic acid segment that encodes a pro-opiomelanocortin polypeptide operably linked to a promoter capable of expressing said segment in a mammalian host cell, and (b) instructions for using said kit in the diagnosis, prevention, or treatment of a pro-opiomelanocortin polypeptide deficiency in said mammalian host cell.

See the teachings of Pritchard et al. recited in previous Office Actions.

Pritchard et al. does not teach the use of recombinant adeno-associated vectors.

Wilson et al. teaches the use of recombinant adeno-associated vectors and virions of AAV serotype 1 as a means for gene therapy, expression of any selected transgene, and delivery to mammalian cells and tissues using cytomegalovirus enhancers/chicken beta-actin promoters (p. 9), in compositions or kits for transfection into host cells. (It is noted that the "instructions" are a physical component of the claimed kit, but are not patentable because they are not

functionally related to the instant composition, see *In re Gulack*, 703 F.2d 1381, 217 USPQ 401 (Fed. Cir. 1983).

See also Dhillon et al. and Bagnasco et al. previously cited in support to show that rAAV vectors were known in the art at the time and commonly used for gene therapy and targeted peptide expression, especially in the mammalian brain, as taught by Wilson et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the POMC peptide of Pritchard et al. and the adeno-associated viral vector of Wilson et al. because Wilson et al. teaches a method to package and deliver specific genes to target cells. Further one of ordinary skill in the art would be motivated to combine the two in order to advance a step in the signaling pathway by starting with the POMC gene expression, and not just the leptin, the signaling precursor to POMC, as indicated in previous Office Actions.

Pritchard et al. teaches the peptides as relates to humans and administration to mice (for example, p. 12, first paragraph), thus it would have been obvious to one of ordinary skill in the art to formulate the compositions for humans, mammalian brains, human brains, in isolated mammalian and human host cells. Further, the recitation of formulations for said purposes recites intended use of the compositions, which do not add further structural limitations to the compounds.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the pro-opiomelanocortin peptide of Pritchard et al. with the recombinant adeno-associated vector of Wilson et al. because Pritchard et. al. and Wilson et al. both teach methods of gene therapy. Further, one of ordinary skill in the art at the time of invention would also have had a reasonable expectation for success

based on the teachings of Pritchard et al., Dhillon et al. cited in support of Pritchard et al., Bagnasco et al. cited in support of Pritchard et al., and Wilson et al. as explained above.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 1, 2, 4, 5, 6, 7-12, 21-38, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pritchard et al. and Wilson et al. in view of Lasic et al.

See the recitations to claims 1, 2, 4, 5, 6, 7, 10-12, 21-38, 40 above.

Claims 8, 9 further recite the composition of claim 1 further comprising a liposome, a lipid, or a lipid complex; further comprising a microsphere or a nanoparticle.

See the teachings of Pritchard et al. and Wilson et al. above.

Pritchard et al. and Wilson et al. do not teach the composition of claim 1 further comprising a liposome, a lipid, or a lipid complex; further comprising a microsphere or a nanoparticle.

See the teachings of Lasic et al. recited in previous Office Actions.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the POMC peptide of Pritchard et al. and the adeno-associated viral vector of Wilson et al. with a liposome or microsphere of Lasic et al. because Lasic et al. teaches the use of the liposome as a means to successfully package and deliver bioactive compounds.

One of ordinary skill in the art at time the invention was made would have a had reasonable expectation of success for using the pro-opiomelanocortin peptide of Pritchard et al. and the recombinant adeno-associated vector of Wilson et al. with the liposome or microsphere

of Lasic et al. because Pritchard et. al. and Wilson et al. and Lasic et al. all teach the delivery of bioactive agents.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 1, 2, 3, 4, 5, 6, 7, 10-12, 21-38, 39, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pritchard et al. and Wilson et al. in view of Paterna et al. ("Influence of promoter and WHV post-transcriptional regulatory element on AAV-mediated transgene expression in the rat brain," Gene Therapy, 7, pp. 1304-1311 (2000)).

See the recitations to claims 1, 2, 4, 5, 6, 7, 11, 12, 21, 24, 26-30, 31-38, 40 above.

Claims 3, 39 recite the composition of claim 1, wherein said rAAV vector further comprises a post-transcriptional regulatory element operably linked to said nucleic acid segment; wherein said post-transcriptional regulatory element comprises a woodchuck hepatitis virus post-transcriptional regulatory element.

See the teachings of Pritchard et al. and Wilson et al. above.

Pritchard et al. and Wilson et al. do not teach wherein said rAAV vector further comprises a post-transcriptional regulatory element operably linked to said nucleic acid segment; wherein said post-transcriptional regulatory element comprises a woodchuck hepatitis virus post-transcriptional regulatory element.

Paterna et al. teaches the use of post transcriptional regulatory element WPRE in rAAVs as a means to enhance in vivo transgene expression (p. 1304).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the POMC peptide of Pritchard et al. and the adeno-associated viral vector of Wilson et al. and the WPRE of Paterna et al. because Paterna et al. teaches that incorporation of the WPRE into the rAAV vectors enhances transgene expression in vivo.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the pro-opiomelanocortin peptide of Pritchard et al. and the recombinant adeno-associated vector of Wilson et al. and the WPRE of Paterna et al. because all teach or suggest methods of gene therapy using peptides and rAAV vectors encoding genes encoding peptides.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Franco Salvoza
Patent Examiner

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600